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Effects On Medication Adherence In HIV-infected Patients By A Part D Style Medication Therapy Management (MTM) Program

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Abstract

Background: Medication Therapy Management (MTM) is a service that is mandated by CMS as part of the Medicare Part D prescription drug program. Patients that meet specific criteria are eligible for clinical reviews of the drug regimens and patient adherence. Ramsell Corporation has implemented a modified MTM program (RamsellMTM™) for Oregon CAREAssist, HIV-infected patients.

Objective: To assess the impact on medication adherence of a modified MTM program in Oregon HIV-infected patients.

Methods: Patients were selected for the MTM program based on a) taking antiretroviral medications (ARV) b) adherence less than 80% c) taking select medications that served as markers for concomitant mental illness or later stage HIV infection. 88 patients were initially enrolled. Services were based on a modified Part D service schedule that included a 30-minute comprehensive medication review (CMR) with the patient via telephone and monthly or quarterly targeted medication reviews (TMR) done as follow ups. All reviews consisted of a thorough clinical review of a medication regimen and detailed adherence counseling. Patients were offered medi-sets and automatic refill options as part of the adherence counseling. Adherence was determined using a standard MPR calculation from pharmacy claims data.

Results: 84 patients have continued in the program. Average time in the program for all patients is 5.3 months. To date, a total of 84 CMRs and 48 TMRs have been conducted. A total of 213 problems have been identified in patient medication therapy (average of 2.53 problems per patient) with 174 problems open, 22 problems resolved (10.3%), and 17 requiring no action from an MTM pharmacist. 71 (80.1%) patients were identified as having adherence being a primary problem at MTM enrollment. The average adherence at entry into the MTM program was 74.4% (+ 4.36 95% confidence intervals). As of 4/15/12, the average adherence for enrolled patients is 79.39% (+ 2.97). The mean difference between time points is +4.98% (p=0.0004).

Conclusion: The modified Part D MTM program has been successful, at an interim time point, in increasing HIV-infected patient's adherence by 4.98%. The program has reached a level of statistical significance. Further validation of adherence intervention is required at later time points.

Background

Recent budgetary pressures have put heavy emphasis on cost-effective delivery of healthcare dollars for many public health entities in the United States. State AIDS Drug Assistance Programs (ADAPs), funded by Ryan White Part B federal funding, are no different. The Health Resources and Service Administration (HRSA) has also mandated that ADAPs implement specific quality assurance measures and programs around the use of the medications paid for by ADAP programs as well as patients adherence to prescribed medication regimens.

The state ADAP programs have responded to this requirement in different ways. The primary way states have responded is through aggressive DUR and DUE process that attempt to quantify and correct any deviations for current treatment guidelines. Other programs have looked at Medication Therapy Management (MTM) programs as a way to ensure quality delivery of healthcare to their clients. MTM encompasses both comprehensive and ongoing reviews of medication regimens, aggressive adherence counseling and interventions, and it involves follow up on identified issues to ensure a high quality of delivered care. In late 2011, Oregon CAREAssist (ADAP) implemented an MTM program with Ramsell Corporation (RamsellMTM™) for their highest need clients.

Methods - General

The program was administered by Ramsell pharmacists via telephone interviews with patients. The MTM program implemented was designed based on the standard MTM model utilized in Medicare Part D clients, with an initial CMR and quarterly TMR. MTM pharmacists could increase the amount of TMRs to monthly at their discretion.

Patients were enrolled based on claims data. Primary enrollment criteria included all of the following: 1) Patients receiving antiretroviral medications. 2) Adherence less than 85% (as calculated by a standard MPR calculation from Oregon CAREAssist claims data, and patients were given priority in enrollment if they were receiving either psychiatric medications (other than anti-depressants) or therapy for Hepatitis C co-infection.

MTM CMRs consist of a comprehensive review of all prescription, over-the-counter (OTC) and herbal/ vitamins/supplements, the patient is taking as part of a 30-minute telephone conversation. Medication regimens are checked for proper medication timing, all interactions, missing and duplicate therapies, and other factors that could decrease the effectiveness of a medication regimen as well as patient adherence to the regimen. TMRs were performed at least quarterly following a CMR or without a CMR if at least 4 attempts to contact the patient had failed. TMRs consisted of a follow up on an issues identified at the CMR, a spot check for new potential issues, and a check on patient adherence. Patient interview for a TMR is encouraged but not required.

Methods - Adherence

Adherence counseling and interventions were performed as part of both the CMRs performed and as a part of the TMRs performed. A basic estimate, prior to medication reviews, was done via a standard Medication Possession ratio (MPR) calculation based on Oregon CAREAssist (ADAP) claims adjudicated through Ramsell systems at the time of each interaction.

In addition to the MPR estimate, self-reported adherence was assessed using a modified version of AACTG self-reported adherence assessment (Chesney et al. AIDS Care. 2000 Jun;12(3):255-66). Patients were also asked their opinion of the calculated MPR and if they thought it was accurate.

Patients were also assessed on when and how they took their medication to ensure that their compliance to the regimen was adequate as well. Adjustments were discussed with patients when issues with regimen compliance (e.g. not taking atovaquone with a high-fat meal) were found. Every effort was made to fit the regimen into the patient's life and lifestyle rather than the other way around. No adherence intervention was standardized, and each intervention was tailored specifically to meet the individual needs of each patient.

Based on the MPR calculation and adherence self assessment, when necessary, the MTM pharmacist then worked with the patient and with their medical provider and social worker/case manager to develop a plan to improve patient adherence. A sample of some of the basic types of interventions used are detailed in Table 1.

As part of the MTM program, Over-the-Counter medications, condoms and medication dose boxes were made available to participating patients free of charge if they desired them.

Sample Adherence Interventions Performed

- Discussion on the importance of adherence
- Discussion of required adherence levels in HIV therapy
- Free medication dose box (once a day or four times a day) given to the patient with instructions for use
- Increase in TMR frequency (up to 1 per month)
- Change in medication storage locations
- Change in medication dosing schedule
- Alternative dosing schedules reviewed
- All adherence interventions were reported to and coordinated with patient's medical provider
- Adverse Event treatment
 - Offering of OTC items for mild adverse events
 - Referral to medical provider for moderate or severe adverse events
- Adverse Event treatment
 - Help in setting up alarms to remind patients to take doses (e.g. smart phone alarms)
- Coordination with case manager on adherence
- Coordination with local pharmacist on adherence
- Placing patient on pharmacy auto-refill
 - Auto-refill was only allowed for CAREAssist patients at the specific recommendation of an MTM pharmacist (n=7 on auto-refill)

Results

- Interim analysis of an observational, real life, cohort
 - Adherence was identified as an issue in 35% of patients (defined as MPR<85%)
 - > Patients with whom adherence was not a major issue still received intensive adherence counseling
 - Average adherence rose in 71 patients (74%) of enrolled patients
 - Average change in adherence by MPR was +12.5% in all enrolled patients.

MTM Program Patient Demographics

OR CAREAssist MTM Eligible Patients Demographics		
Sex	n	Total Eligible (n=437)
Male	86	89.6%
Female	10	10.4%
Ethnicity		
Caucasian	59	61.5%
African American	4	4.2%
Asian	1	1%
Native American/Hawaiian	1	1%
Hispanic/Latino	10	10.4%
Unknown/Other	21	21.9%

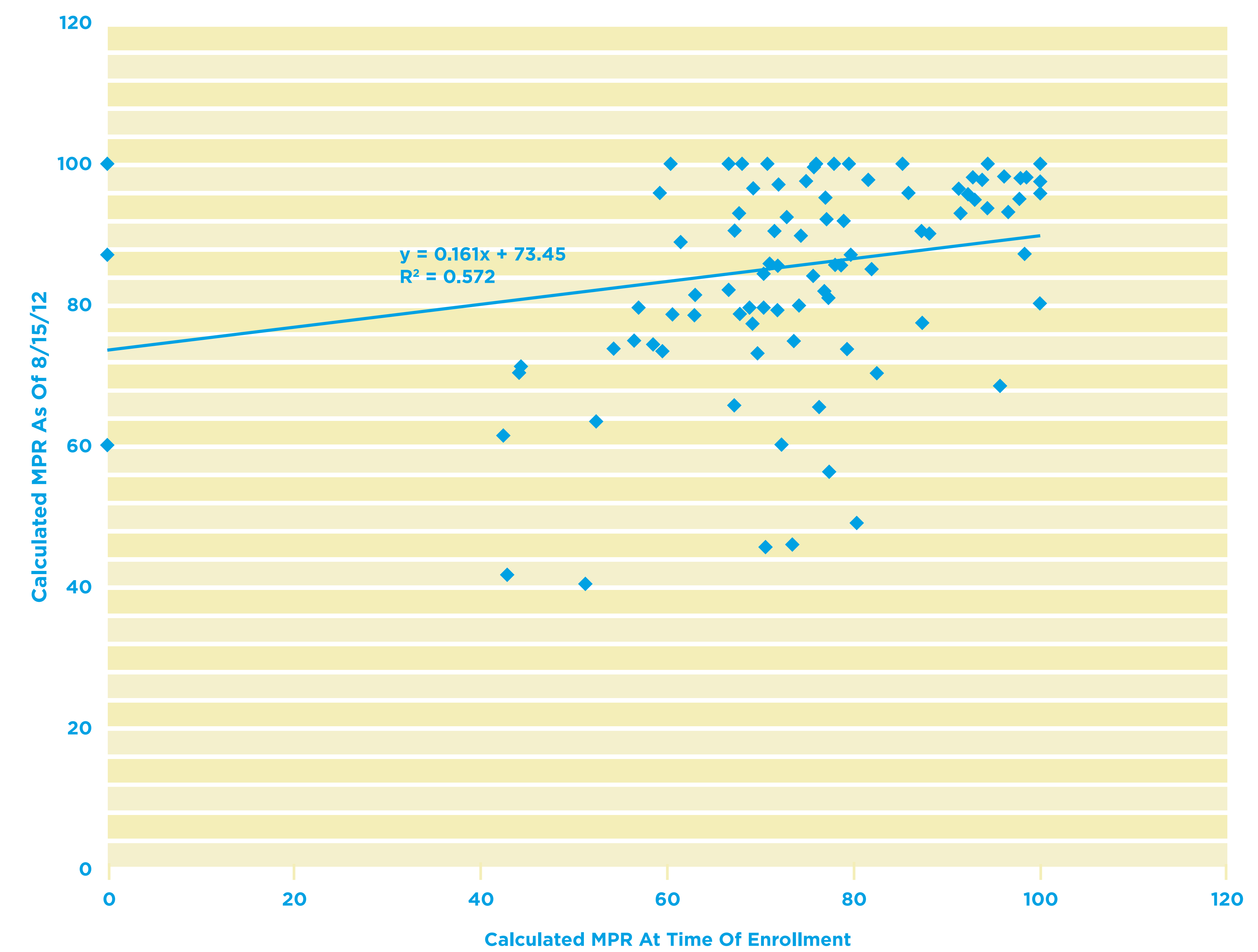
MTM Program General Statistics

Total Enrolled Patients	96	
CMRs Completed	84	
TMRs Completed	165	
Total Interactions	249	
Total Issues Identified	324	
Average Number of Identified Issues Per Patient	3.375	
Patients Utilizing Auto-Refill Per Recommendation of MTM Pharmacist	3.375	

Classification of Issues Identified		
Issue	Total	% of Total
Adherence Counseling	113	34.88%
Adverse Event	30	9.26%
Drug-Disease Interaction	10	3.09%
Drug-Drug Interaction	75	23.15%
Duplicate Therapy	14	4.32%
Missing Therapy	24	7.41%
Substitute Therapy	4	1.23%
Non-Standard Dosing	6	1.85%
Other/Not Specified	48	14.81%
Current Issue Status		
Status	Total	% of Total
Open	189	58.33%
Closed	58	17.90%
No Action Required	37	11.42%

Adherence Data Summary	
MPR At Enrollment	72.63%
Std Dev.	21.90
95% Confidence Intervals	+/-4.44
MPR As Of 8/15/12	85.14%
Std Dev.	14.74
95% Confidence Intervals	+/-2.99
Change In MPR	12.51%
P Value (T-Test, 2 Tailed, Independent Data)	p=0.0000078
Changes in MPR Values Enrollment to 8/15/12	
Mean Time In Program (months)	9.49
Number Of Patients With Increasing MPR Values	71
Mean Increase	20.32
Median Increase	15.41
Std Dev.	9.86
95% Confidence Intervals	+/- 4.03

Paired Calculated MPR Values From Enrollment To 8/15/12



Conclusions

- MTM services may be effective in improving adherence in HIV infected individuals
- Allowing multiple options that tailor the adherence intervention to the individual needs of the patient may be worth further exploration and research

Limitations

- Observational nature of the cohort does not allow control for adherence placebo affect of program participation
- MPR as an adherence measure has many inaccuracies and may grossly overestimate or underestimate actual adherence depending on circumstance
- Even in its limited use, auto-refill may cause MPR to be distorted to show better adherence than actual patient adherence interim time point analysis
- Interim time point analysis
- Lack of tracking of individual adherence measures does not allow full details on which aspects of the intervention are most effective